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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,464

08/25/2003

James D. Ralph

F-286

8288

51640

7590

06/03/2009

SPINE MP

LERNER, DAVID, et al.

600 SOUTH AVENUE WEST

WESTFIELD, NJ 07090

EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/648,464

Applicant(s)

RALPH ET AL.

Examiner

JAVIER G. BLANCO

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 18, 20, 21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18, 20, 21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2009 has been entered.

Response to Amendment

2. Applicants' amendment of claims 13, 16, 21, 29, 32, and 35 in the reply filed on January 16, 2009 is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 25, the "deflectable porous surface" lacks antecedent basis. Claim 26 depends from claim 25.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13-16, 18, 20, 21, and 23-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No.:

6,673,113

6,669,731

6,887,273

6,645,249

6,610,092

6,863,689

6,869,446

6,887,273

Art Unit: 3774

6,989,032

6,932,844

7,169,182

7,118,599

7, 101,399

7,022,139

7,258, 699

7,044, 969

7,060,098

7,066, 959

7,163,559

7,044, 970

7,115,132

7,235,081

7,141,069

7,141,070

7,144,426

7,186,268

7,223,290

7,261,739

7,160,327

7,491,241

Art Unit: 3774

7,491,241

7,491,241

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 13-16, 18, 20, 21, and 23-35 of the application and the claims of the above-indicated patents lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of the claims of the above-indicated patents is in effect a “species” of the “generic” invention of claims 13-16, 18, 20, 21, and 23-35. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 13-16, 18, 20, 21, and 23-35 of the application are anticipated by the claims of the above-indicated patents, it is not patentably distinct from the claims of the above-indicated patents.

Please note, independent claims 13, 16, and 21 are generic as to the particular shape (e.g., arched strip; washer; sleeve; skirt; etc.) of the spring/socket. The above-indicated patents claim, in more detail, the particular shape (e.g., washers, arched strips, sleeves, skirt, etc.) of a spring/socket having a volume/opening for receiving (or receiving) a rounded or ball-shaped structure (or post). This was previously indicated in the 37 CFR 1.105 REQUIREMENT FOR INFORMATION.

7. Claims 13-16, 18, 20, 21, and 23-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the most-current (i.e., recently amended) pending claims of the following copending Application No.:

10256160
10706766

Art Unit: 3774

10715969

10725297

10725296

10782981

11037921

11208664

10784597

10282356

10294983

10294989

10294980

10294984

10294986

10294982

10294988

10294985

10294981

10309585

10642523

10642524

10642522

09970479

10642528

10642528

10140153

10151280

10256160

10256160

10725305

10782981

10782981

10833737

10783152

10784597

10294982

10282356

10282356

10294983

10294983

10294989

10294989

10294980

10294980

10294984

Art Unit: 3774

102949841029498610294986102949821029498810294988102949851029498510294981102949811030958510309585104252671064252210642522106425231064252310642524106425241064252610642526

Although the conflicting claims are not identical, they are not patentably distinct from each other because the above-mentioned applications also claim a resilient spring/socket for receiving a rounded or ball-shaped structure. Please note, independent claims 13, 16, and 21 are generic as to the particular shape (e.g., arched strip; Belleville washer; sleeve; skirt; etc.) of the spring/socket. The Applicants have numerous other co-pending applications and issued patents claiming, e.g., Belleville washers, arched strips, sleeves, skirt, etc. as the spring/socket. Also note, several applications have been amended to include a scope that also read on the claims of the instant application

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This was previously indicated in the 37 CFR 1.105

REQUIREMENT FOR INFORMATION.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 13, 16, 18, 20, 21, 23, 27, 30, and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Hoffman** (DE 2263842 A).

Referring to Figures 7 and 8, Hoffman discloses an intervertebral spacer device comprising a first plate (e.g., top plate) having an inner surface and an exterior surface; a second plate (e.g., bottom plate) having an inner surface and an exterior surface, the inner surface of the first and second plates facing one another; wherein said inner surface of said first plate comprises a ball-shaped structure extending therefrom (**Figure 7**: ball-shaped structure comprising 26, or 26 + post extending from 25; **Figure 8**: ball-shaped structure comprising 36, or 36 + post extending from 35), said ball-shaped structure having a curved convex surface directed away from said inner surface of said first plate (clearly seen in Figures 7 and 8), and said inner surface of said second plate having a resilient deformable spring (Figure 7: 28; Figure 8: 28) affixed thereto at one or more locations (Figures 7 and 8 clearly show attachment at least at 27, 29) such that at said one or more locations there is no movement of said spring relative to said second plate in any direction, said spring being monolithically formed and having a curvate volume (e.g., central opening) *for receiving and holding therein* said ball-shaped structure, a top side

with a curved convex surface that extends from the curvate volume and confronts said inner surface of said first plate and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate (see Figures 7 and 8). Each of 26 and 36 is capable of being inwardly deflected.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). With regards to statements of intended use and other functional statements (e.g., *deformable; for receiving; permits; for counteracting; is movable; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Hoffman**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. Claims 13, 16, 18, 20, 21, 23, and 27-35 are rejected under 35 U.S.C. 102(e) as anticipated by **Ralph et al.** (US 5,989,291; previously cited in PTO-892) or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Ralph et al.** (US 5,989,291; previously cited in PTO-892) in view of either one of **Berry** (US 5,895,428; cited in Applicants' IDS), **Bryan et al.** (US 6,156,067; cited in Applicants' IDS), or **Harrington** (US 5,893,889 A; cited in Applicants' IDS).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex (see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9). The ball attached with one of the plates is ball-shaped head 207. The resilient deformable spring/socket affixed with the other one of said plates is spring 230, which is monolithically formed, and it is affixed thereto at one or more locations such that at said one or more locations there is no movement of said spring relative to said second plate in any direction (e.g., once assembled, the spring/socket is locked/fixed to the fitting or plate). As seen in Figures 8 and 9, the spring/socket having a top side with a curved convex surface that extends from the curvate volume 232/233 and confronts said inner surface of said first plate and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate. Regarding claims 28, 31, and 34, Figure 9 clearly shows

the spring as having at least one hole (as part of the curvate volume) extending therethrough and a fastener extending through the at least one hole.

a. The term “affixed” is commonly defined as “to secure to something”. The spring/socket 230 will be secured at one or more locations once the prosthesis is assembled since the assembly will prevent physical separation. Once assembled, the spring/socket is affixed to the plate. Ralph et al. ‘291 disclose spring/socket 230 as “compressible retained in the interior of the device”. Even if the second plate will shift from left to right, spring/socket 230 will be affixed and secured to the second plate.

b. Berry ‘428 discloses (see Figure 11) the subject matter of affixing a spring/socket (e.g., fitting 109; fitting 109 + fitting 105) to a plate at one or more locations (e.g., threads 111,123) in order to prevent movement of said spring relative to said plate. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of affixing a spring/socket to a plate at one or more locations, as taught by Berry ‘428, with the spring/socket of Ralph et al. ‘291, in order to prevent movement of said spring relative to said plate.

c. Bryan et al. ‘067 disclose (see Figures 6, 9, and 10) the subject matter of using threaded fasteners (e.g., screw 362; screw 92) in order to attach a spring/socket (e.g., spring 250; spring 320) to an intervertebral plate (see plates 322, 324). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using threaded fasteners, as taught by Bryan et al., with the spring/socket of Ralph et al. ‘291, in order to attach said spring to an intervertebral plate.

d. Harrington ‘889 teaches (see Figure 2) a spring/socket (54) having holes (60) aligned with holes (52, 53) in a second plate (49), and having fasteners (64, 66) extending through each of said holes in order to securely fix the spring to the second plate (see column 3, lines 52-57). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a spring having holes aligned with holes in a second plate, and having fasteners extending through each of said holes, as taught by Harrington, with the spring/socket of Ralph et al. ‘291, in order to securely fix the spring to the second plate.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). With regards to statements of intended use and other functional statements (e.g., *deformable; for receiving; permits; for counteracting; is movable; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Ralph et al.**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danyl*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb*

Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ralph et al.** (US 5,989,291; previously cited in PTO-892) in view of **Stubstad et al.** (US 3,867,728 A; cited in Applicants' IDS).

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh

21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

Response to Arguments

Applicant's arguments with respect to claims 13, 16, and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on **(571)272-4749**. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738